FzioMed, Inc.

170-A Granada Drive
San Luis Obispo, CA 93401
Ph 805.546.0610
Fax 805.546.0571

8115 '00 FEB -8 P2:27

February 4, 2000

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fisher Lane, rm. 1061
Rockville, MD 20852

Ref: Docket No. 99D-5199
"Guidance for Resorbable Adhesion Barrier Device for Use in Abdominal and/or Pelvic Surgery"

To Whom It May Concern:

Please see and forward the attached letter to Dr. Elisa Harvey, (Ob/Gyn Branch/ODE/CDRH), concerning comments regarding the draft "Guidance for Resorbable Adhesion Barrier Device for Use in Abdominal and/or Pelvic Surgery".

Thank you very much.

Sincerely,

Thomas G. Juarez
Director, Regulatory Affairs

99D-5199

C 1

FzioMed, Inc.

170-A Granada Drive
San Luis Obispo, CA 93401
Ph 805.546.0610
Fax 805.546.0571

February 4, 2000

Elisa Harvey, D.V.M., Ph.D.
Obstetrics & Gynecology Devices Branch
HFZ-470
ODE, CDRH, FDA
9200 Corporate Blvd.
Rockville, MD 20850

Dear Dr. Harvey:

FzioMed, Inc. is a research and development company in San Luis Obispo, CA involved in the development and manufacture of absorbable adhesion barrier medical devices. We have reviewed the draft guidance document on resorbable adhesion barrier devices and appreciate the opportunity to comment on several points of the proposed regulation.

We share the views recently expressed at the FDA Panel Meeting January 25, 2000, in Gaithersburg, MD. by the Adhesion Barrier Task Force, the ad-hoc group formed by members of industry, academia, and clinicians. In particular, we support the notion of establishing industry guidelines in consideration of the least burdensome approach promulgated in the FDA Modernization Act of 1997 (FDAMA). In addition, we would like to reiterate certain key points.

As stated by several speakers at the 1/25/00 advisory panel meeting, and has been cited many times in the literature, post-surgical adhesion reduction/prevention should be considered a clinical end-point, in and of itself. It is generally accepted in the medical community that these adhesions are a phenomenon that are likely to contribute to many of the medical conditions which have been previously proposed as "real" clinical end-points, e.g., infertility, pain, and bowel obstruction. Quite frankly, given the added burden of requiring the assessment of these "real" end-points, small, innovative development companies such as ours would cease to exist. FzioMed appreciates the possible need during post-marketing studies to gather this relative information, but does ask that the FDA use caution in defining the scope of this proposal.

In addition, FzioMed, Inc. has had extensive discussions with members of the medical surgical community in relation to (dis)similarities of adhesion formation following laparoscopy vs laparotomy surgical procedures. FzioMed feels very strongly that the FDA should not implement a default regulation requiring separate pivotal studies. Assuming the sponsor is able to make the argument that the device works equally well for either procedure, given the similarity in adhesion formation and mechanism of device operation, and that the device is shown in pilot studies to be safe for both procedures, it should be up to the sponsor to make the argument that the device is approvable for both indications.

FzioMed, Inc. very much appreciates the FDA's efforts, and in particular those of your office, in drafting a guidance document which, after consideration of industry's input, will evolve into one where there is consensus among all concerned.

Sincerely,

FzioMed, Inc.

Thomas G. Juarez
Director, Regulatory Affairs

Align top of FedEx PowerShip Label here.

FedEx
emp# 114328 04FEB00

** 2DAY **

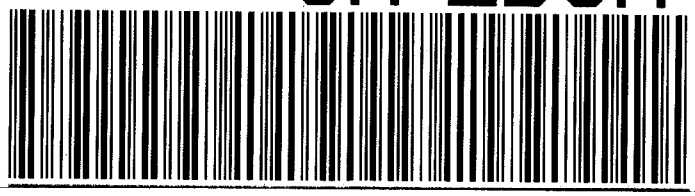
TUE

Deliver By:
8FEB00
AA

TRK# 8157 7751 0113 FORM 0215

20852 -MD-US

IAD
SA EDGA



FedEx USA Airbill FedEx Tracking Number 8157 7751 0113

Form I.D. No. 0215

Recipient's Copy

1 From This portion can be removed for Recipient's records.

Date 2/4/00

FedEx Tracking Number 815775100113

Sender's Name Tom Juarez Phone 805 546 0610

Company FZIOMED INC

Address 170 GRANADA DR STE A

Dept./Floor/Suite/Room

City SAN LUIS OBISPO State CA ZIP 93401

2 Your Internal Billing Reference

3 To

Recipient's Name Dockets Mgmt. Branch HFA-305 Phone 301 594-3090

Company Food & Drug Admin.

Address 5630 Fisher Lane Rm. 1061

We cannot deliver to P.O. boxes or P.O. ZIP codes.

Dept./Floor/Suite/Room

To "HOLD" at FedEx location, print FedEx address here.

City Rockville State MD ZIP 20852

4a Express Package Service — Packages up to 150 lbs. Delivery commitment may be later in some areas.

- [ ] FedEx Priority Overnight — Next business morning
- [ ] FedEx Standard Overnight — Next business afternoon
- [ ] FedEx First Overnight — Earliest next business morning delivery to select locations
- [x] FedEx 2Day* — Second business day
- [ ] FedEx Express Saver* — Third business day

* FedEx Letter Rate not available. Minimum charge: One-pound rate

4b Express Freight Service — Packages over 150 lbs. Delivery commitment may be later in some areas.

- [ ] FedEx 1Day Freight* — Next business day
- [ ] FedEx 2Day Freight — Second business day
- [ ] FedEx 3Day Freight — Third business day

* Call for Confirmation:

5 Packaging — * Declared value limit $500

- [x] FedEx Letter*
- [ ] FedEx Pak*
- [ ] Other Pkg. — Includes FedEx Box, FedEx Tube, and customer pkg.

6 Special Handling

- [ ] Saturday Delivery — Available for FedEx Priority Overnight and FedEx 2Day to select ZIP codes
- [ ] Sunday Delivery — Available for FedEx Priority Overnight to select ZIP codes
- [ ] HOLD Weekday at FedEx Location — Not available with FedEx First Overnight
- [ ] HOLD Saturday at FedEx Location — Available for FedEx Priority Overnight and FedEx 2Day to select locations

Does this shipment contain dangerous goods? One box must be checked.

- [x] No
- [ ] Yes — As per attached Shipper's Declaration
- [ ] Yes — Shipper's Declaration not required
- [ ] Dry Ice — Dry Ice, 9, UN 1845 ____ x ____ kg

Dangerous Goods cannot be shipped in FedEx packaging.

- [ ] Cargo Aircraft Only

7 Payment Bill to: Enter FedEx Acct. No. or Credit Card No. below.

- [x] Sender — Acct. No. in Section 1 will be billed.
- [ ] Recipient
- [ ] Third Party
- [ ] Credit Card
- [ ] Cash/Check
- [ ] Obtain Recip. Acct. No.

Total Packages: 1 Total Weight: 1 Total Charges

Credit Card Auth.

†Our liability is limited to $100 unless you declare a higher value. See the *FedEx Service Guide* for details.

8 Release Signature — *Sign to authorize delivery without obtaining signature.*

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

Questions? Call 1·800·Go·FedEx® (800-463-3339)
Visit our Web site at www.fedex.com

SRP 999 • Rev. Date 11/98 • Part #154813S • © 1994-98 FedEx • PRINTED IN U.S.A.

359

8157 7751 0113

0115995309